UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,389	12/28/2001	Gholam-Reza Zadno-Azizi	PERCUS.113A	4551

20995 7590 10/07/2003

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
HAN, MARK K	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 10/07/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/035,389	Applicant(s) ZADNO-AZIZI, GHOLAM-REZA
	Examiner Mark K Han	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29,31-44,46 and 47 is/are rejected.

7)☒ Claim(s) 30,40,41 and 45 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 28 December 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claims 40 and 41 are objected to because of the following informalities: "the occlusive device" of claim 40 and "the inflatable balloon" of claim 41 lack sufficient antecedent basis. For the purposes of this Office Action, it is assumed that claim 40 depends from claim 39 and claim 41 depends from claim 40. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 9-11, 15-29, 31-44, 46 and 47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of U.S. Patent No. 6,135,991. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader in some respects and adds features in other respects. *In re Goodman*, 11 F.3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993).

3. Claims 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,135,991 (hereinafter

"Muni") in view of U.S. Patent No. 5,092,841 to Spears. Muni discloses the claimed invention except that a general fluid is used instead of a anticoagulant/thrombolytic agent. Spears suggests using a thrombolytic agent for treating an arterial lesion. See col. 7, lines 22 through col. 8, line 34. It would have been obvious to one of ordinary skill in the art to substitute a anticoagulant/thrombolytic agent, as suggested by Spears, for the fluid of Muni in order to facilitate removal of thrombolytic material and to prevent restenosis.

4. Claim 14 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,135,991 in view of U.S. Patent No. 5,588,962 to Nicholas et al. (hereinafter "Nicholas"). Muni discloses the claimed invention except the use of a radioactive drug. Nicholas discloses a radioactive drug. Nicholas suggests using a radioactive drug to an arterial lesion. See col. 6, lines 42-65. It would have been obvious to one of ordinary skill in the art to substitute a radioactive drug, as suggested by Nicholas, for the fluid of Muni as an alternative means to reduce restenosis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4 and 36-41 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent no. 5,087,244 to Wolinsky et al. (hereinafter "Wolinsky").

Wolinsky discloses a method of delivering fluid through the wall of a balloon 16 on wire 10. Hence, the fluid contacts the occlusive device. See cols. 2-6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of U.S. Patent No. 5,092,841 to Spears.

Wolinsky discloses the claimed invention except that heparin is used instead of a thrombolytic agent. Spears suggests using a thrombolytic agent for treating an arterial lesion. See col. 7, lines 22-35. It would have been obvious to one of ordinary skill in the art to substitute a thrombolytic agent, as suggested by Spears, for the heparin of Wolinsky in order to facilitate removal of thrombolytic material.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of Nicholas.

Wolinsky discloses the claimed invention except the use of a radioactive drug. Nicholas discloses a radioactive drug. Nicholas suggests using a radioactive drug to an arterial lesion. See col. 6, lines 42-65. It would have been obvious to one of ordinary skill in the art to substitute a radioactive drug, as suggested by Nicholas, for the heparin of Wolinsky as an alternative means to reduce restenosis.

8. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of U.S. Patent No. 5,810,767 to Klein.

Wolinsky discloses the claimed invention except for the flow rate of drug delivery. Klein suggests a flow rate from 1 ml/min to 40 ml/min (or 0.0167 cc/sec to 0.67 cc/sec). See col. 11, lines 55-60. It would have been obvious to one of ordinary skill in the art to modify the invention of Wolinsky to deliver the fluid at a rate suggested by Klein in order to provide efficient drug delivery.

Allowable Subject Matter

9. Claims 30 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K Han whose telephone number is 703-308-4543. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mkh

Mark Han
Patent Examiner
Art Unit 3763

mkh
September 30, 2003

MANUEL MENDEZ
PRIMARY EXAMINER